UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

In re LANTUS DIRECT PURCHASER ANTITRUST LITIGATION	)	Civil Action No. 16-12652-LTS

ORDER ON DEFENDANT'S MOTION TO STRIKE IMPROPER REBUTTAL REPORTS[1]
[Docket No. 535]

November 12, 2024

Boal, M.J.

Sanofi-Aventis U.S., LLC seeks to strike three of plaintiffs' rebuttal expert reports as untimely. Docket No. 535 at 1. For the following reasons, I deny the request.

I. FACTUAL AND PROCEDURAL BACKGROUND

A. The Plaintiffs' Allegations

This case alleges antitrust violations on the part of the defendant, Sanofi-Aventis U.S., LLC. The case originally sought damages for purchases of the following products: Lantus (insulin glargine sold in vials and/or cartridges) and Lantus SoloStar (insulin glargine in a pre-filled injector pen). The plaintiffs alleged that Sanofi improperly submitted for listing in the FDA's Orange Book both (1) two polysorbate formulation patents for Lantus cartridges, and (2) a series of pen-related patents for Lantus SoloStar. The current plaintiffs only seek damages for Lantus SoloStar premised on the improperly listed pen patents. Docket No. 535 at 1.

[1] Judge Sorokin referred the case for full pretrial, dispositive motions to the undersigned on July 31, 2024. Docket No. 530.

B. Procedural History

On December 13, 2023, Judge Sorokin adopted the parties' proposed discovery schedule. Docket No. 510. That schedule provided that the party with the burden of proof must serve opening expert reports "for all issues other than Economic Issues" by May 31, 2024. Docket No. 507 at 2. It also clarified that "[o]n this date, Sanofi shall serve the opening expert report(s) on the issue of whether its submission of the Device Patents to FDA for listing in the Orange Book 'was the result of a reasonable, good-faith attempt to comply with the Hatch-Waxman' statute and regulations" and that "[t]he Plaintiffs shall serve opening expert reports on all other issues (other than Economic Issues) on this date." Id. at 1 n.2. Opposing expert reports were due on August 2, 2024. Id. at 2. Rebuttal expert reports were due on September 6, 2024. Id. The deadline for Rule 56 motions and Daubert motions was November 1, 2024, and the deadline for oppositions to such motions was December 13, 2024. Id. at 2-3.

C. Disagreement Over Whether Plaintiffs' Rebuttal Expert Reports Were Improper

Sanofi asserts that plaintiffs' allegations are still that Sanofi improperly submitted both device patents and formulation patents for Orange Book listing. Docket No. 536 at 3. In support, Sanofi relies on each of the amended complaints and the plaintiffs' interrogatory responses. Id. at 3 n.3, 5-8. Moreover, Sanofi asserts that even if plaintiffs are now only seeking damages for improperly listed device patents, they still need to show that both the device patents and formulation patents were improperly submitted. See Docket No. 544 at 2-7. Sanofi explains that "[t]he Formulation Patents provided an independent basis for a statutory stay of FDA approval for competing versions of the Lantus SoloStar, and broke the chain of causation between Sanofi's alleged misconduct in listing and enforcing the Device Patents and any claim for damages flowing from those actions." Id. at 2. Therefore, plaintiffs should have submitted

opening expert reports by the May 31 deadline to support their allegations that Sanofi improperly listed the formulation patents and "addressing how the allegedly improper listing of the Formulation Patents delayed FDA approval for, or the launch of, any follow-on products and thereby injured Plaintiffs." Docket No. 536 at 10. Because they did not, Sanofi asserts that they were forced to put forth expert reports anticipating plaintiffs' arguments, thereby reversing the logical order of expert briefing which benefitted plaintiffs. Id. at 10-11.

On the other hand, plaintiffs assert that Sanofi's motion ignores the evolution of this eight-year-old case. Plaintiffs are now "*only* seek[ing] damages for Lantus SoloStar, premised *only* on the improper listed pen patents." Docket No. 542 at 5 (emphasis in original). Accordingly, plaintiffs assert that their "opening expert reports need only address issues in the plaintiffs' case-in-chief (i.e., improper listing and suing on pen patents submitted for listing under Lantus SoloStar); they do not need to address moot issues related to Lantus (i.e., improper listing and suing on polysorbate [formulation] patents)." Id. at 6. Plaintiffs therefore dispute Sanofi's contention that the formulation patents are necessary to prove causation under the current allegations. Id. at 7.

Nevertheless, to cure any possible prejudice, plaintiffs offer that Sanofi be allowed to:

> ([i]) serve additional, supplemental expert reports responding specifically to the plaintiffs' experts' September 13, 2024 opinions concerning the polysorbate patents, ([ii]) depose plaintiffs' experts either before or after serving defendants' supplemental reports, and ([iii]) put off the depositions of defendant's experts expected to serve supplemental reports . . .

Id.[2]

[2] Plaintiffs added that the only constraints they seek are that "Sanofi's supplemental expert reports should only address matters its experts had not previously addressed concerning the polysorbate patents (as many spilled significant ink on this issue already) and that those reports should be due, and expert depositions should occur, before summary judgement briefing begins

II. ANALYSIS

A. Legal Standard

Rule 26 of the Federal Rules of Civil Procedure requires a party to disclose the identities of expert witnesses that it may use to present evidence at trial. Fed. R. Civ. P. 26(a)(2)(A). Barring a stipulation or court order, "this disclosure must be accompanied by a written report." Fed. R. Civ. P. 26(a)(2)(B). The report must contain "a complete statement of all opinions the witness will express and the basis and reasons for them." Id. Such disclosures must be made "at the times and in the sequence that the court orders." Fed. R. Civ. P. 26(a)(2)(D).

Preclusion of expert testimony is "one of the harshest sanctions available." Lawes v. CSA Architects & Engineers LLP, 963 F.3d 72, 92 (1st Cir. 2020). It "is not a strictly mechanical exercise; district courts have some discretion in deciding whether or not to impose that onerous sanction." Santiago-Diaz v. Laboratorio Clinico Y De Referencia Del Este And Sara Lopez, M.D., 456 F.3d 272, 276 (1st Cir. 2006) (citing Jackson v. Harvard Univ., 900 F.2d 464, 468–69 (1st Cir. 1990)).

B. Assessment

The parties present different views of the plaintiffs' burden of proof and that burden's impact on the order of expert reports. Because plaintiffs present a plausible theory regarding its burden and given that preclusion of expert testimony is a harsh sanction, this Court finds that the better course is to deny the motion but afford Sanofi the measures proffered by plaintiffs. Accordingly, Sanofi may: (1) serve additional, supplemental expert reports responding specifically to the plaintiffs' experts' September 13, 2024 opinions concerning the polysorbate

(on November 1, 2024)." Docket No. 542 at 7. The timing request is now moot, and this Court declines to adopt the constraint as construed by the Plaintiffs.

patents; (2) depose plaintiffs' experts either before or after serving its supplemental reports; and (3) put off the depositions of Sanofi's experts expected to serve supplemental reports until a date determined by the parties. The parties shall meet and confer regarding dates by which these tasks must be accomplished. They shall file a scheduling proposal, jointly if possible, separately if necessary, by November 19, 2024. Any such scheduling proposal must also include dates for the remaining discovery deadlines, Rule 56 motions, and Daubert motions.

III. ORDER

For the foregoing reasons, this Court denies Sanofi's motion.

/s/ Jennifer C. Boal
JENNIFER C. BOAL
United States Magistrate Judge